



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/049,695	03/27/98	BILLING-MEDEL	6066.US.PI

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EXAMINER

SUN HOFFMAN, L

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 04/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/049,695

Applicant(s)

Billing-Medel et al

Examiner

First Last

Group Art Unit

1234

☐ Responsive to communication(s) filed on 1/31/00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-3, 7-10, 16, and 19-27 is/are pending in the application.

Of the above, claim(s) 7-10, 16, and 19-27 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1642

DETAILED ACTION

1. Claims 4-6, 11, 12, 15, 17 and 18 are canceled.

Claim 1 is amended.

Claims 7-10, 13-14 and 16, drawn to ~~non~~^{non}-elected inventions, remain withdrawn from examination.

Claims 19-27 are entered as new claims

2. Newly submitted claims 19-27 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the invention is directed to a method of diagnosis, classified in class 435, subclass 6.

Inventions of claims 1-3 and claims 19-27 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of polynucleotide can be used in other methods, such as in vivo gene therapy.

Since applicants have received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 19-27 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Therefore, claims 1-3 are examined on the merits.

Rejections withdrawn:

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3. Rejections under 35 USC § 101 to claims 17 and 18 are withdrawn.

Rejections under 35 USC § 112 to claims 1-6, 12, 15, 17-18 are withdrawn.

Rejections under 35 USC § 102 to claims 1, 2, 4-6, 11, 15, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al (Genbank accession number AA299977; Nature, vol 377, Supp., page 3-16, 28, Sept. 1995), are withdrawn.

Rejections under 35 USC § 103 to claims 1, 3, 5, 6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al or Hillier et al (see Genbank EST, accession number T78178, submitted on March 15, 1995; and accession number T85589, submitted on March 17, 1995) in view of Olson et al. US Patent No. 4,889,806 and Sambrook et al (Molecular Cloning, a Laboratory Manual, 1989, Cold Spring Harbor Press, p. 16.3-4), are withdrawn.

Rejection Maintained

Oath/Declaration

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Applicants claimed priority under U.S.C. 120 in the first line of the specification, wherein the current application is a CIP of US application 08828845. The oath and declaration file on 6/28/98, in Paper No. 5 fails to claim such priority.

New Grounds for Rejections:

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Specification

5. The amendment filed on 1/27/2000 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: SEQ ID NO:25 has only 97.7% of identity to the SEQ ID NO: 5 (clone 958984) in parent case 08828845.

Applicants are required to cancel the new matter in the reply to this Office action.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial utility or a well-established utility.

The disclosed utilities are for diseases associated with breast. However, neither the specification nor any art of record teaches what the polynucleotide (CS197) is and what it does. The specification does not teach a utility for any of the fragments claimed, does not teach a relationship to any specific diseases or establish any involvement in the etiology of any specific diseases. The asserted utilities for CS197, such as production of and detecting diseases apply to many unrelated polypeptide structures sequences. Therefore the asserted utilities are not considered "specific" utilities, i.e., they are not specific to CS197 protein as well as its cDNA or EST sequence.

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The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed nucleic acids.

Claim Rejections - 35 USC § 112

7. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The SEQ ID NO:25 is not supported by the parent application 08828845. SEQ ID NO:5 in the parent application has only 97.7% identity to the SEQ ID NO: 25.

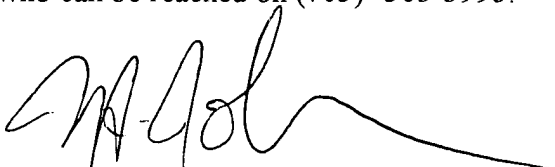
Conclusion

8. No claim is allowed. Claims are free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lin Sun-Hoffman, Ph.D., whose telephone number is (703)-308-7552. The examiner can normally be reached on Monday to Friday from 7:30 am to 4:00 pm Eastern Standard Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputal, Ph.D., who can be reached on (703) -305-3995.

Lin Sun-Hoffman, Ph.D.


NANCY A. JOHNSON, PH.D
PRIMARY EXAMINER

April 5, 2000